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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------|---------------------|------------------|
| 10/773,792 | 02/06/2004 | Thomas W. Dubensky JR. | 282172002900 | 8458 |
| 25226 | 7590 | 10/03/2006 | EXAMINER | |
| MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018 | | | GRASER, JENNIFER E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/773,792 | DUBENSKY ET AL. | |
| | Examiner | Art Unit | |
| | Jennifer E. Graser | 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-21, drawn to an isolated Listeria bacterium which is attenuated for entry into non-phagocytic cells and comprises a nucleic acid molecule encoding a non-Listerial antigen and antigen-presenting cells comprising said bacterium and methods of treatment/prevention using said cells, classified in class 435, subclass 252.3.
 - II. Claims 22-41, drawn to an isolated Listeria bacterium which is attenuated *both* for entry into non-phagocytic cells *and* for cell-to-cell spread, classified in class 435, subclass 252.4.
 - III. Claims 42-48, drawn to a strain identified by accession # PTA-5562, classified in class 435, subclass 252.1.
 - IV. Claims 42-48, drawn to a *mutant* of strain #PTA-5562 which is defective with respect to both internalin B and Acta, classified in class 435, subclass 172.1.
 - V. Claims 49-58, drawn to vaccines comprising Listeria bacterium which is attenuated for entry into non-phagocytic cells and antigen-presenting cells comprising said bacterium (does not require the nucleic acid encoding a non-Listerial antigen as the composition of Group I), classified in class 424, subclass 234.1.

- VI. Claim 59, drawn to a method of inducing MHC class I antigen presentation or MHCII presentation on an antigen-presenting cell, classified in class 424, subclass 235.1.
- VII. Claim 60, drawn to a method of inducing an immune response to *any* antigen (non-Listerial or Listerial), classified in class 424, subclass 203.1.

The inventions are distinct, each from the other because of the following reasons:

2. The Inventions of Groups I, II, III, IV and V comprise different products which are biologically, chemically and structurally different. The bacterial cell of Group I does not require an mutation or attenuation for cell-to-cell spread as is required by Group II. The bacteria of Group V does not require the nucleic acid encoding a non-Listerial antigen as the composition of Group I. The bacterial deposit of Group II does not have the mutation which is in the bacterium of Group IV. The methods of Group VII do not require the specific bacterium of any of the preceding Groups. The method of Group VI is unrelated to the method of Groups I-V and VII since it uses a different bacterial cell, e.g, one which comprises an antigen which comprises an MHC class I epitope or MHC class II epitope. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification and recognized divergent subject matter and because the literature search for the groups would not be coextensive, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species:

Group I.

Species: Applicant must elect the specific mutation which is to occur, e.g., a mutation in actA; a mutation in actA and plcB, a mutation in inIB, actA and plcB, etc..

The species are independent or distinct because they represent completely different gene sequences, structures and mutations.

Group II.

Species: Applicant must elect the specific mutation which is to occur, e.g., a mutation in actA; a mutation in actA and plcB, a mutation in inIB, actA and plcB, etc..

The species are independent or distinct because they represent completely different gene sequences, structures and mutations.

Group V.

Species: Applicant must elect the specific mutation which is to occur, e.g., a mutation in actA; a mutation in actA and plcB, a mutation in inIB, actA and plcB, etc..

The species are independent or distinct because they represent completely different gene sequences, structures and mutations.

Group VI.

Species: Applicant must elect the specific mutation which is to occur, e.g., a mutation in actA; a mutation in actA and plcB, a mutation in inIB, actA and plcB, etc..

The species are independent or distinct because they represent completely different gene sequences, structures and mutations.

Art Unit: 1645

Group VII.

Species: Applicant must elect the specific mutation which is to occur, e.g., a mutation in actA; a mutation in actA and plcB, a mutation in inIB, actA and plcB, etc..

The species are independent or distinct because they represent completely different gene sequences, structures and mutations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 5, 6, 10, 13, 14, 15, 16-19, 20-22, 25-27, 32-39, 40, 41, 49, 50, 54-60 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

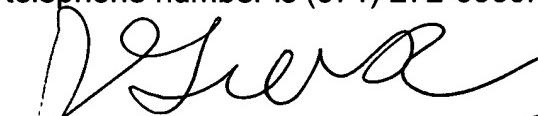
remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 (which is able to receive transmissions 24 hours/day, 7 days/week).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Navarro, can be reached on (571) 272-0861.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.


Jennifer Graser
Primary Examiner
Art Unit 1645
